MAY 0 3 2002

K020554

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Kinetikos Medical, Inc. 4115 Sorrento Valley Blvd. San Diego, CA 92121 Telephone (858) 558-2233 FAX (858) 558-0838
Official Contact:	John Spampinato
Representative/Consultant:	Floyd G. Larson PaxMed International 4329 Graydon Road San Diego, CA 92130 Telephone (858) 792-1235 FAX (858) 792-1236

DEVICE NAME

Classification Name:	Wrist joint metal/polymer semi-constrained cemented prosthesis
Trade/Proprietary Name:	Universal Total Wrist™ System
Common Name:	Wrist Prosthesis

PREDICATE DEVICE INFORMATION

The principal predicate device for this modification is the Kinetikos Medical Universal Total Wrist™ System, cleared by FDA on June 6, 1996 under K961051.

PACKAGING/LABELING/PRODUCT INFORMATION

Packaging and labeling of the device will be the same as that of the present Universal Total Wrist. The device will continue to be indicated for cemented use only.

INTENDED USE

The KMI Universal Total Wrist™ System is indicated for intractable pain resulting from traumatic arthritis, osteoarthritis, rheumatoid arthritis, and trauma-induced osteoarthritis of the radial/carpal joints. It is intended to replace functionality of the joint due to deformity or elements stated above. It is intended for cemented use only.

SYSTEM DESCRIPTION

The KMI Universal Total Wrist™ (UTW) System (either predicate or modification) consists of the following components: the radial implant, the carpal plate implant, the carpal polymer component and two bone screws. The system is offered in three sizes (small, medium, and large), with three matching polymer component sizes, which are available in varying thicknesses (standard, +1 mm, +2 mm). It is constructed of materials that have a long clinical history of proven acceptance and performance. This system is intended for use with cement and will be promoted as such in the UTW surgical technique manual.

Material Composition

There is no change in material composition of the device, except for addition of a CP Ti porous bead coating to the Ti-6Al-4V carpal plate. The Co-Cr-Mo porous bead coating added to the radial component is of the same material as the component.

EQUIVALENCE TO MARKETED PRODUCT

The modification to the UTW has the following similarities to the predicate UTW, which previously received 510(k) concurrence:

- has the same indicated use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same materials (with the addition of porous coatings), and
- is packaged and sterilized using the same materials and processes.

In summary, the modification to the Kinetikos Medical Universal Total Wrist™ System described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 3 2002

Floyd G. Larson
Kinetikos Medical Inc.
c/o PaxMed International
4329 Graydon Road
San Diego, California 92130

Re: K020554
Trade/Device Name: Universal Total Wrist System
Regulation Number: 21 CFR §888.3800
Regulation Name: Wrist joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWJ
Dated: February 19, 2002
Received: February 20, 2002

Dear Mr. Larson;

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

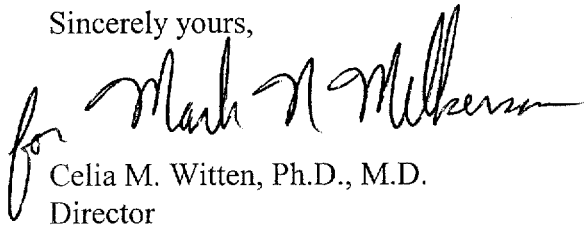
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Device Name: Universal Total Wrist™ System

K020554 page 1 of 1

Indications for Use:

Indicated for intractable pain resulting from traumatic arthritis, osteoarthritis, rheumatoid arthritis, trauma-induced osteoarthritis of the radial/carpal joint. To replace functionality of the joint due to deformity or elements stated above. Intended for cemented use only.

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020554

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_____